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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DALEY
Appln. No.	:	09/670,781
Conf. No.:	:	6751
Filed:	:	September 27, 2000
Title:	:	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTION
Group Art Unit	:	1761
Examiner	:	WEINSTEIN, S.
Docket No.	:	00-39 RCE 1

* * * * *

April 30, 2007

REPLY BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents and Trademarks
Alexandria, VA 22313-1504

Dear Sir:

This Reply Brief is filed under 37 C.F.R. §41.41 in reply to the Examiner's Answer mailed March 1, 2007. Appellant hereby requests that the Appeal be maintained.

Appellant submits that this Reply Brief is being timely submitted (non-extended due date: May 1, 2007).

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on April 30, 2007 with sufficient postage as "Express Mail Post Office to Addressee" in an envelope addressed to:

Mail Stop Appeal Brief -Patent, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Express Mail Label No. EV 196265150 US .

Timothy Nathan, Reg. No. 44,256

In the Answer, the Examiner recites many of the same arguments previously presented. Accordingly, the Appellant hereby reasserts the positions fully presented in the Appeal Brief submitted on November 13, 2006. In addition, Appellant submits the following arguments to respond to issues raised in the Examiner's Answer.

A. Argument

At page 10 of the Examiner's Answer, the Examiner contends that the Applicant has argued limitations not present in the claims. Applicant respectfully submits that this argument lacks merit. The Examiner states that "[m]uch of the appellant's urgings are directed to single use containers, with the implication of a small amount of product. It is noted, however, that many of the claims do not positively recite a volume of total product vis-à-vis the container." (Examiner's Answer, at p. 10, ll. 1-5). First, the Examiner correctly points out that the allegedly omitted language does appear in claims 12 and 17. On that basis alone, the Examiner is incorrect in stating that the Appellant has argued limitations not found in the claims. These allegedly "missing" limitations do appear in claims 12 and 17. Secondly, the only time the noted language is recited in the Appellant's Appeal Brief is at page 4 with respect to claims 12 and 17, page 7 quoting the Examiner, and page 8 again quoting the Examiner.

An examiner typically makes this argument during prosecution when an applicant has argued that the prior art does not teach a claim element which, through oversight, happens to be omitted from the currently pending claims. This is simply not the case in the present Application. The Appellant's arguments with respect to the prima facie case are that the

Examiner's rejections apply nonanologous art, and that the art of record lacks any suggestion to modify or combine the references as suggested by the Examiner. The Appellant fails to see how this could be construed as arguing missing limitations. The Examiner has propped up an imaginary fact pattern and proceeded to respond to it.

At page 10 of the Examiner's Answer, the Examiner's conclusion that the container art and the children's medical device art are within the same field of endeavor lacks merit. What is clear is that the Examiner has expanded the field of endeavor to encompass every field from which he could find a reference that supports his rejection. In addition, the Examiner states that ". . . the art taken as a whole teaches that the recited sucrose solution in bulk quantity is well established in the art." This seems to imply that one of ordinary skill in the children's medical device art is also an expert in containers and packaging. The Examiner then concludes that such an expert would find the Appellant's invention obvious. This is an incorrect conclusion based on an incorrect assumption. What was known in the art was that the use of sucrose solutions could be used to relieve procedural pain in neonates. (See, e.g., Stevens et al., Acta Paediatr 86:837-42, 1997; Stevens et al., Nursing Research Jan/Feb Vol. 48, No. 1, 1999; and Blass, Pediatrics, Vol. 87, No. 2, 1991.) As noted in the Physician's Affidavits, the state of the art was for a nurse, doctor, or pharmacist to hand-mix these solutions. The Examiner cannot credibly argue that nurses, doctors, or pharmacists are in anyway skilled in the container and packaging art or that the container and packaging art is within the same fields as children's medical devices.

As for defining the problem sought to be solved, the Examiner mischaracterizes the state of the art at the bottom of page 10 of the Examiner's Answer, and states that "[i]f the problem is that the sucrose solution in bulk containers is not convenient, unsanitary and wasteful, where else would one look but in the container art where all types of products are contained in all types of containers." This quote demonstrates that the Examiner fails to appreciate that the problem to be solved by the present invention was that physicians were not using sucrose solutions even though sucrose was known to alleviate the suffering of infants. The Appellant asserts that the problem to be solved was the time involved, inconsistency in hand-mixing, and potential contamination. In response, the Examiner states at page 12 that the "Applicant did not 'invent' these sources of the problem nor was he the first to recognize them." First, the Appellant is not aware of any statutory requirement that an applicant must "invent" the sources of the problem solved. An inventor needs to satisfy the requirements of 35 U.S.C. §§ 101-103 and create new, useful, and nonobvious statutory subject matter.

The Applicant disagrees with the Examiner's second statement: the Appellant did identify the source of the problem. The Examiner attempts to characterize the problem as one which merely involves the problems inherent in the use of large bulk containers, and then concludes that it would be obvious to invent the present invention. This conclusion presupposes that the "problem" was the use of bulk containers. Once again, the use of bulk containers was not the problem the inventor was presented with. The problem was that physicians were not using sucrose solutions. It was found that this was because of the time involved, the inconsistency of hand-mixed solutions, and potential contamination. Presented with this

problem, the Appellant found a simple and elegant solution which, as highlighted in Ms. Bush's affidavit, has met with surprising commercial success.

At page 13 of the Examiner's Answer, the Examiner concluded that Ms. Bush's affidavit is defective, and has questioned that it is unclear how effective the heel-warmer was at providing pain relief. This position misses the point. The heel-warmer is another children's medical product sold by the same company, at the same time, using the same marketing channels, to the same customers. And, while the heel-warmer has been successful, it did not meet with the extreme success of the SWEET-EASE product which is an embodiment of the present invention. The Appellant sells no other analgesic product that directly competes with the SWEET-EASE™ product. This information was presented to provide objective, substantiating evidence to support Ms. Bush's assertion that the SWEET-EASE™ product sales have been surprisingly extraordinary. Rather than giving this evidence due consideration, the Examiner has chosen to overlook Ms. Bush's assertion and attack the supporting evidence.

At page 14 of the Examiner's Answer, the Examiner discounts the affidavits filed by the Physicians and again raises the same argument presented previously in the Examiner's Answer that the affidavits are directed to subject matter not present in the claims. However, the affidavits contain no language directed to single dose/serve products as alleged by the Examiner. There are simply no facts to support the Examiner's conclusion. The Physicians Affidavits are further evidence of patentability, and should be given due consideration. In addition, it should be noted that the Examiner's Answer failed to even comment on the evidence submitted by the Appellant which demonstrated copying by others subsequent to the release of the SWEET-EASE

product. This, too, is evidence of patentability which should be given due consideration by the Examiner. Collectively, it is clear that the Examiner has not properly considered the Applicant's secondary considerations demonstrating surprising commercial success, long-felt but unresolved need, and copying by others. Once the secondary considerations are properly construed, the Appellant asserts that the claims of the present Application are patentable.

B. Conclusion

For the reasons set forth above as well as those fully articulated in the Appellant's Appeal Brief, the rejections of the appealed claims are improper and should be reversed.

Respectfully submitted,

By_____

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